Rep. Roe statement on ANS to H.R. 1016 4/21/15

Thank you, Mr. Chairman. It's a pleasure to present this amendment in the nature of a substitute to H.R. 1016, the Biological Implant Tracking and Veteran Safety Act.

A frightening GAO report in January 2014 found that the VA does not use a standardized process for tracking biological tissue from a cadaver donor to a living veteran recipient. In the event of a recall, it would be virtually impossible to track down which patient had received contaminated tissue. The same GAO report detailed that the Veterans Health Administration does not always ensure it is purchasing tissue from biological implant vendors that have registered with the FDA, and does not maintain an inventory system to prevent the expired tissues from remaining in storage alongside unexpired tissues.

The GAO and VA committee staff have discovered that VA often uses a loophole in Title 38 of US Code 8123 that allows it to buy biological

implants on the open, unregulated market, which it does in 57% of its biological implant purchases. H.R. 1016 would require the procurement of biological implants from vendors on Federal Supply Schedules, which have been appropriately vetted. For biological implants not on the Federal Supply Schedule, but requested by clinicians, my bill requires justification and approval of open market purchase under the Federal Acquisition Regulation on case by case basis, rather than simply granting a blanket waiver as provided in Title 38.

H.R. 1016, as amended, would direct the Secretary of Veterans Affairs to adopt FDA's Unique Device Identification system for labeling of all biological implant tissue and implement an automated inventory system to track the tissue from donor to implant recipient. This legislation would also require all biological implant tissue be procured through vendors that are registered with the FDA, accredited by the American Association of Tissue Banks, and use FDA's Unique Device Identification system.

This amendment in the nature of a substitute conforms H.R. 1016 to legislation offered in the Senate by my good friend and fellow physician, Senator Bill Cassidy. The technical improvements include:

- Clarification of citations to FDA provisions
- Deletion of inspection and audit requirement in lieu of already existing FDA responsibility
- Extension of record retention from 5 to 10 years.

The 6 million veterans served annually by VHA deserve the highest standard of patient care in the nation. Implementation of H.R. 1016 would help establish VA as the industry leader in biologic implant safety and accountability. I want to thank the Oversight and Investigations subcommittee staff for their help in developing this legislation which truly puts veteran patients first. Thank you, Mr. Chairman. I yield the balance of my time.